



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-2588]

### Quantitative Brain Amyloid Positron Emission Tomography Imaging in Patients with Alzheimer's Disease; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Quantitative Brain Amyloid PET Imaging in Patients with Alzheimer’s Disease.” The purpose of the public workshop is to evaluate the role of quantitative positron emission tomography (PET) measures of amyloid deposition in the brain in clinical trials and clinical use in patients with suspected or confirmed Alzheimer’s disease.

**DATES:** The public workshop will be held on November 17, 2022, from 8:30 a.m. to 5 p.m. Eastern Time. Submit either electronic or written comments on this public workshop by December 19, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA White Oak Campus Great Room. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/about-fda/visitor-information>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 19, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 19, 2022. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2022-N-2588 for “Quantitative Brain Amyloid PET Imaging in Patients with Alzheimer’s Disease.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Kyong “Kaye” Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 301-796-1970, [Kyong.Kang@fda.hhs.gov](mailto:Kyong.Kang@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

I. Background

Alzheimer’s disease (AD) is a major public health concern worldwide and its accurate diagnosis and staging is critical for the optimal management of patients at risk for or afflicted with this devastating disorder. The accuracy of clinical diagnosis of AD by dementia experts is modest when compared to postmortem diagnosis. Amyloid burden is one of the pathological hallmarks of the disease, and in patients presenting with cognitive and memory disturbances, quantitative imaging of brain amyloid offers the potential to enhance the assessment and management of patients with suspected or confirmed AD. This workshop aims to evaluate the role of quantitative PET measures of amyloid deposition in the brain in clinical trials and as well as in clinical use in patients with suspected or confirmed AD.

II. Topics for Discussion at the Public Workshop

The workshop will provide an overview of clinical and investigational uses of brain amyloid PET imaging, the regulatory history of marketed imaging drug products and devices for amyloid quantitation, clinical pharmacology of tracers, quantitation methodology, metrics and analytical validity, and use of quantitative amyloid in clinical trials with perspectives from industry, trade and professional organizations, academic investigators, and patient advocacy group.

III. Participating in the Public Workshop

*Registration:* To register for the public workshop, persons interested in attending this public workshop virtually or in-person must register online by November 16, 2022, 11:59 p.m.

Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. No same-day registration will be available.

Registration is free and in-person participation is limited due to space availability constraints; therefore, FDA may limit the number of onsite participants from each organization. Registrants will receive confirmation when they have been accepted. If there are COVID-19 restrictions in place at the time of the event, this conference will move to an all-virtual event.

If you need special accommodations due to a disability, please contact Kyong “Kaye” Kang no later than November 16, 2022.

*Streaming Webcast of the Public Workshop:* This public workshop will also be webcast at [https://fda.zoomgov.com/webinar/register/WN\\_ezA-\\_Y94QMSaT0SHBdlS5g](https://fda.zoomgov.com/webinar/register/WN_ezA-_Y94QMSaT0SHBdlS5g).

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/drugs/news-events-human-drugs/fda-cder-cdrh-snmml-and-mita-workshop-quantitative-brain-amyloid-pet-imaging-patients-alzheimers>.

**Dated:** October 21, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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